REQUEST FOR RECONSIDERATION

Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 as presented with applicants' reply dated February 16, 2006, and resubmitted on May 11, 2006, are currently pending in this case.

The Examiner reiterated the position that the subject matter of applicants' Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 was unpatentable under 35 U.S.C. §103(a) in light of the teaching of ***Ortega et al.*** **(US 4,837,032).**

When applying 35 U.S.C. §103, it is inter alia necessary that the reference(s) be considered as a whole, that the reference(s) suggest the desirability and thus the obviousness of making the claimed combination, and that the references be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.[1] Applying these tenets of patent law, three basic criteria have to be met in order to establish a *prima facie* case of obviousness:

(1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings,

(2) there must be a reasonable expectation of success, and

(3) the prior art reference or the combined references must teach or suggest all of the claim limitations.

Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and cannot be based on the applicant's disclosure.[2]

Citing references which merely indicate that the elements which are recited in a claim are separately known in the art is not a sufficient basis for concluding that the combination of the elements which is set forth the claims would have been obvious to a person of ordinary skill in the art.[3] To render the claimed combination of elements obvious it is necessary that there be evidence of a motivating force which would impel a person skilled in the art to do what the applicant has done. The mere fact that the prior art could be

1) *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

2) *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)

3) Cf. *Ex parte Hiyamizu*, 10 USPQ2d 1393 (BPAI 1988).

combined and/or modified so as to arrive at the applicant's invention as claimed does not suffice to render such a modification *prima facie* obvious unless the prior art suggests the desirability of the modification.[4] Also, the fact that the respective combination and/or modification is within the skill in the art does not allow a conclusion that the prior art provides for a motivation to make the pertinent combination and/or modification.[5] "Would have been able to produce" does not meet the standards applicable to a determination under Section 103(a).[6]

1. REGARDING THE PROCESS OF CLAIMS 1 TO 9, 12, 13, 16, AND 27 TO 32:

When the teaching of ***Ortega et al.*** is considered as a whole, without the benefit of impermissible hindsight vision afforded by applicants' invention, the reference clearly fails to suggest the desirability and thus the obviousness of making the combination necessary for the claimed process. The reference also fails to teach or suggest all of the elements of applicants' claims, and fails to provide the suggestion or motivation which was necessary for a person of ordinary skill to produce an oral dosage form with sustained release of active ingredient, wherein the dosage form comprises

a) a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone which acts as a binder and a matrix former, and wherein

the polyvinylpyrrolidone has a molecular weight of from 20,000 to 1,000,000, and

the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate,

b) at least one active ingredient,

c) optionally water-soluble polymers or low or high molecular weight lipophilic additives,

d) and, optionally, excipients,

by ganulating a mixture of a) to d) or a) to c) or a) and b) and d)

4) Cf. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); see also, eg., *Interconnect. Planning Corp. v. Feil*, 774 F.2d 1132, 227 USPQ 543 (Fed. Cir. 1985); *In re Grabiak*, 769 F.2d 729, 226 USPQ 870 (Fed. Cir. 1985); *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983).

5) Cf. *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998); *Al Site Corp. v. VSI International, Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

6) *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986).

or a) and b) by heating to a temperature of from 40°C to 130°C in the absence of solvents.

The teaching of ***Ortega et al.*** describes a preparation of theophylline tablets by:[7)]

> *compounding the theophylline with the acid insoluble polymer, preferably to a particle size of less than 30 mesh.*
>
> *The resulting mixture may then be blended and wet granulated with a portion of the film former [*inter alia PVP*] in a solution such as ethyl alcohol in the case of polyvinylpyrrolidone.*
>
> *The granulate may then be sized through a sieve, optimally 16 mesh,*
> *mixed with the remaining film former [*inter alia PVP*], the insoluble polymer [*inter alia PVAc*] (also optimally powdered to less than 30 mesh) and the lubricant.*
>
> *The resulting mixture may then be compressed using a standard rotary tablet press.*

Additionally, the reference provides in the context of illustrative Example 1:[8)] *"The dried granulate was sized through a 16 mesh sieve, and then transferred to a V-blender. 9 kg of polyvinyl acetate (particle size less than 30 mesh) was added plus 6 kg of polyvinylpyrrolidone and 3 kg of the lubricant mix (stearic acid: talc: magnesium stearate 3:1:0.5). All the ingredients were mixed for 20 minutes. The granulate so obtained was compressed into tablets ..."*

The Examiner argued:[9)] *"It is this dried theophylline based product [*obtained after drying the granulate*] that is combined with PVP and PVA and lubricant and the granules from this step are formulated into tablets. ... Therefore, Ortega discloses the process of claim 1 with respect to the process where 1 a) and 1 b) are granulated. Ortega does not indicate that solvent is used in the second step. The claim does not state any particular order of adding the components. Therefore, with respect to applicant's argument, Ortega discloses all the elements of the claims as described above."*

It is immediately apparent, however, that the Examiner's argument fails to appreciate applicants' requirement that the mixture comprising (a) and (b) be granulated *"by heating to a temperature of from 40°C to 130°C in the absence of solvents."* The teaching of ***Ortega et***

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7) Cf. col. 4, indicated lines 1 to 13, of ***US 4,837,032***.

8) Cf. col. 4, indicated lines 34 to 42, of ***US 4,837,032***.

9) Final Office action page 7, lines 4 to 11.

al. clearly fails to suggest or imply that the mixing step be conducted at an elevated temperature. ***Ortega et al.*** merely state that the polymers were added to a certain mixer and were mixed for 20 minutes. In contrast thereto, applicants' claim requires that the components be heated to a temperature of from 40 to 130°C for granulation. The Examiner asserted:[10] *"Ortega discloses a process of wet granulating a mixture of theophylline, polyvinylpyrrolidone cellulose[,] acetate phthalate; the dried granulate is then combined with mixture of polyvinylpyrrolidone, polyvinyl acetate and lubricant, which is a mixture ... [of] stearic acid, magnesium stearate and talc (abstract; column 2, lines 56-68; column 3, lines 57-63; and column 4, lines 3-18) at a temperature of 40°C to 50°C (example 1)."* The Examiner's summary of the facts is incorrect and misleading. The temperature of 40°C to 50°C is employed by ***Ortega et al.*** to dry the product obtained in the initial wet granulation step:[11] *"... The wet mass was dried in a fluid bed dryer at 40°C-50°C. for 30 minutes. The dried granulate was sized ..."* The reference does not specify any particular temperature concerning the step of mixing the dried granulate with the other components.

Also, ***Ortega et al.*** neither teaches nor suggests that the dried granulate be combined with a *"mixture of polyvinylpyrrolidone, polyvinyl acetate and lubricant"* as the Examiner would have it. In the general description of the procedure, ***Ortega et al.*** state:[12] *"The [dried] granulate may then be seized through a sieve, ..., mixed with the remaining film former, the insoluble polymer (...), and the lubricant. The resulting mixture may then be compressed ..."* The description of illustrative Example 1 of the reference correspondingly sets forth:[13] *"The dried granulate was sized ..., and then transferred to a V-blender. 9 kg of polyvinyl acetate (...) was added plus 6 kg of polyvinylpyrrolidone and 3 kg of the lubricant mix (stearic acid: talc: magnesium stearate 3:1:0.5)."* The polyvinyl acetate and the polyvinylpyrrolidone which are employed in this stage of the prior art process are, accordingly, not mixed before they are added to the dried granulate, and the cited sections of the reference can clearly not suggest or imply a *"formulated mixture of polyvinyl acetate and polyvinylpyrrolidone ... wherein ... the polyvinylpyrroli-*

10) Final Office action page 4, lines 3 to 7; emphasis added.

11) Cf. col. 4, indicated lines 29 to 34, of ***US 4,837,032.***

12) Cf. col. 4, indicated lines 7 to 11, of ***US 4,837,032.***

13) Cf. col. 4, indicated lines 33 to 38, of ***US 4,837,032.***

done is finely dispersed in the polyvinyl acetate," as required in accordance with applicants' component (a).

Additionally, the Examiner's argument fails to appreciate that applicants' process requires more than merely a combined use of powdered PVP and powdered PVAc. Applicants' component (a) is *"a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone which acts as a binder and a matrix former, and wherein ... the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate."*[14] It is well known in the chemical art that a dispersion is a two phase system where one phase consists of finely divided particles (often in the colloidal size range) distributed throughout a bulk substance, the particles being the disperse or internal phase and the bulk substance being the continuous or external phase.[15] ***Ortega et al.***'s second step entails, as noted above, that polyvinyl pyrrolidone and polyvinyl acetate be mixed for a period of 20 minutes. The respective mixture of the distinct polymers can, however, clearly not be deemed to correspond to, or to teach, suggest or imply, the particularities of the formulated mixture which employed as component (a) in accordance with applicants' process. Also, as previously pointed out by applicants,[16] PVP and PVAc are not miscible with one another so that simple combination of the polymers, even by way of a homogeneous melt, is not possible. Merely mixing the polymers, as is done in accordance with the teaching of ***Ortega et al.*** can, therefore, not reasonably be considered to form a formulated mixture of PVP and PVAc in which finely divided particles of PVP are dispersed throughout a continues phase of the PVAc.

The Examiner took the position:[17] *"The claim does not state any particular order of adding the components."* Applicants respectfully disagree. Applicants' claims require that component (a) be a certain *"formulated mixture of polyvinyl acetate and polyvinylpyrrolidone."* It is therefore clearly required that the constituents of applicants' component (a) be present in the form of said formulated mixture before the mixture is granulated with the active ingredient (b) and optionally one or more of the further components.

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14) Cf. Claim 1, emphasis added.

15) Cf. e.g. ***Hawley's*** Condensed Chemical Dictionary, 13th Ed. 1997, page 417, a copy of which is herewith enclosed for the Examiner's convenience.

16) Cf. applicants' paper dated February 16, 2006. The entire paper is herein incorporated by reference.

17) Final Office action page 7, line 9.

For at least the foregoing reasons, the Examiner's position that ***Ortega et al.*** disclose all of the elements of applicants' Claim 1 is deemed to be in error. The teaching of ***Ortega et al.*** is in light of the foregoing remarks, and in light of the arguments previously presented by applicants,[18] clearly unsuited to establish that the subject matter of Claim 1 is unpatentable under Section 103(a). Claims 2 to 9, 12, 13, 16 and 27 to 32 depend upon Claim 1, and if an independent claim is non-obvious under 35 U.S.C. §103, then any claim depending therefrom is non-obvious.[19] Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is, therefore, respectfully solicited.

2. REGARDING THE DOSAGE FORM OF CLAIMS 17 TO 23 AND 33:

The teaching of ***Ortega et al.***, considered as a whole without the benefit of impermissible hindsight vision afforded by applicants' invention also clearly fails to suggest the desirability and thus the obviousness of making the combination necessary for the claimed dosage form. Again, the reference fails to teach or suggest all of the elements of applicants' claims, and fails to provide the suggestion or motivation which was necessary for a person of ordinary skill to produce an oral dosage form with sustained release of active ingredient, wherein the dosage form comprises

a) a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone wherein the polyvinylpyrrolidone has a molecular weight of from 20,000 to 1,000,000, and the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate,

b) at least one active ingredient,

c) optionally water-soluble polymers or low or high molecular weight lipophilic additives,

d) and, optionally, excipients,

wherein the mixture of a) to d) or a) to c) or a) and b) and d) or a) and b) is granulated by heating to a temperature of from 40°C to 130°C.

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18) Cf. applicants' papers dated August 10, 2004, March 07, 2005, and February 16, 2006. The respective arguments and remarks are herein incorporated by reference.

19) *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

The Examiner pointed out:[20] *"how the composition is made carries no patentable weight because product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps; and 'even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.'"* In other words: the manipulations per se have no limiting effect on a product which is defined in terms of product-by-process claim; however, the structure which is implied by the steps has to be taken into consideration. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established.[21] Those circumstances are, however, not applicable in the present case.

As already explained in the discussion regarding Claim 1, the ***Ortega et al.*** reference fails to teach or suggest a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone wherein the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate. It has also been pointed out in that context that the mixture which is obtained in the second step of ***Ortega et al.***'s procedure by mixing polyvinyl pyrrolidone and polyvinyl acetate for a period of 20 minutes, cannot reasonably be deemed to correspond to, or to teach, suggest or imply, the particularities of the formulated mixture which constitutes component (a) of applicants' dosage form. As such, the reference fails to teach or suggest all of the elements of applicants' claims, and fails to provide the suggestion or motivation which was necessary for a person of ordinary skill to modify the prior art tablets. Accordingly, the prior art process and applicants' process cannot be considered to be *"identical or substantially identical."*

Additionally, considering the particularities of applicants' component (a), applicants' product cannot be deemed to be *"identical or substantially identical"* with the prior art tablet. As noted in the

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20) Final Office action page 3, line 17, to page 4, line 3.

21) *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

foregoing, ***Ortega et al.***'s procedure entails that a comminuted mixture of the active ingredient and the acid insoluble polymer is wet granulated with a film forming polymer such as polyvinylpyrrolidone, ie. the active ingredient is brought into intimate contact with, or even embedded in, the film forming polymer. Only after the product of the wet granulation has been dried and seized, the granules are mixed with further film former and with PVAc. This means that the product obtained in the procedure of ***Ortega et al.*** comprises the active ingredient primarily surrounded by the acid insoluble polymer and the film forming polymer.

Applicants' process comprises granulating the active ingredient with *"a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone ... wherein the polyvinylpyrrolidone ... is finely dispersed in the polyvinyl acetate,"* ie. with a mixture in which the polyvinyl acetate constitutes the continuous or external phase in which the polyvinylpyrrolidone is dispersed.[15)] This means that the product obtained in accordance with applicants' process provisions comprises the active ingredient primarily surrounded by the polyvinyl acetate.

The teaching of ***Ortega et al.*** is in light of the foregoing remarks, and in light of the arguments previously presented by applicants,[15)] clearly unsuited to establish that the subject matter of Claim 17 is unpatentable under Section 103(a). Claims 18 to 23 and 33 depend upon Claim 17, and the respective embodiments are, therefore, also not obvious under 35 U.S.C. §103.[16)] Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is, therefore, respectfully solicited.

3. REGARDING THE METHOD OF CLAIM 25:

The foregoing remarks are equally applicable where the subject matter of applicants' Claim 25 is concerned which pertains to a *"method of delaying the release of at least one active ingredient comprising producing the oral dosage form of claim 17 wherein the at least one active ingredient comprises food supplements or additives, vitamins, minerals or trace elements."* (*emphasis added*). As emphasized in the foregoing partial reproduction of Claim 25, the pertinent elements of Claim 17, ie. the components which are mandatory as well as the procedural measures, are incorporated by reference.

The teaching of ***Ortega et al.*** is, therefore, also deemed to be unsuited to establish that the subject matter of Claim 25 is unpatentable under Section 103(a). Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is respectfully solicited.

The Examiner also reiterated the position that the subject matter of applicants' Claims 1 and 8 was unpatentable under 35 U.S.C. §103(a) in light of the teaching of ***Ortega et al.*** (**ibid.**) when taken n view of the disclosure of ***Noda et al.*** (**US 5,389,380**).

The Examiner applied the secondary reference for teaching a theophylline composition which contains lactose or starch or mannitol excipient. ***Noda et al.***'s disclosure adds nothing to the teaching of ***Ortega et al.*** which could reasonably supplement the suggestion or motivation which is necessary for a person of ordinary skill in the art to modify ***Ortega et al.***'s tablets, or the process employed in accordance with ***Ortega et al.***'s teaching, as is necessary to arrive at the dosage forms, or the method or the process which is defined in applicants' claims. The disclosure of ***Noda et al.*** is equally unsuited to teach or suggest any of the limitations of applicants' claims which are missing from the teaching of ***Ortega et al.*** Even when the disclosure of ***Noda et al.*** is included in the consideration, at least two of the three basic criteria for establishing a prima facie case of obviousness are not met, and the references cannot reasonably be taken to establish that the subject matter of applicants' respective claims was prima facie obvious within the meaning of Section 103(a).

In light of the foregoing it is respectfully urged that the rejection of Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 under 35 U.S.C. §103(a) based on the teaching of ***Ortega et al.*** and the disclosure of ***Noda et al.*** be withdrawn. Favorable action is solicited.

The Examiner rejected Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 under 35 U.S.C. §112, ¶1, asserting that applicants' disclosure of the claimed invention failed to comply with the written description requirement. In particular, the Examiner argued:[22] *"The claim(s) contain subject mater, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant*

22) Final Office action page 2, lines 14 to 17.

art that the inventor(s), at the time the application was filed, had possession of the claimed invention" because:[23] *"There is no description of what 'finely dispersed' is and there is no description of how polyvinylpyrrolidone is 'finely dispersed' in the polyvinyl acetate."*

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.[24] An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.[25] Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.[26] Also, an application need not teach, and preferably omits, that which is well known in the art.[27]

Applicants show possession of the invention in particular by describing various examples, ie. an actual reduction to practice, on pages 12 to 21, of the application. In those examples, applicants employed a commercially available product, ie. Kollidon® SR. Accordingly, formulated mixtures of polyvinyl acetate and polyvinylpyrrolidone in which polyvinylpyrrolidone was finely dispersed in the polyvinyl acetate were, at the time applicants filed the application, well known in the art. Additionally, applicants have provided a copy of a U.S. patent of ***Kolter et al.***, ie. US 6,066,334,[28] which further

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23) Final Office action page 2, lines 17 and 18.

24) See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

25) *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

26) See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991)

27) Cf. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

28) Cf. applicants' paper dated February 16, 2006.

corroborates that the manner in which polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate was known in the art at the time the application was filed.

Since an application need not teach, and preferably omits, that what is well known in the art, and possession of the invention may be shown by an actual reduction to practice, the Examiner's position that the specification fails to convey that applicants had possession of the invention is deemed to be in error.

It is respectfully requested that the rejection of Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 under 35 U.S.C. §112, ¶1, be withdrawn. Favorable action by the Examiner is solicited.